

**REMARKS**

Claims 1-8 were pending. Without acquiescing to any of the Examiner's arguments, while expressly reserving the right to prosecute same or similar claims in subsequent applications, the Applicant has cancelled claims 1-8 and, in the amendment set out above, introduced new claims 9 – 12.<sup>1</sup>

The Examiner made the following objections and rejections.

- (1) The Examiner rejects claims 1 and 3-6 under 35 U.S.C. §102(b).
- (2) The Examiner rejects claims 2, 7 and 8 under 35 U.S.C. §103(a).

The Applicant's remarks are presented in the same order as the rejections set out above.

**1. The Claims Are Not Anticipated**

In order to further business interests, and without acquiescing to the Examiner's arguments (while expressly reserving the right to prosecute the claims as originally filed or claims similar thereto) the Applicant has introduced new independent claims (i.e. claims 9 and 13) which recite, in part, methods for administering, "a rapid dissolving sublingual dosage form comprising tramadol and propoxyphene."

The Examiner rejects claims 1 and 3-6 as anticipated by U.S. Patent 6,261,599 B1 to Oshlack *et al.* By the Examiner's own admission, however, "Oshlack *et al.* do not teach [a] sublingual dosage form. . .".<sup>2</sup> A single reference must disclose each limitation of a claim in order for that reference to anticipate the claim. See, *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984). The Applicant submits the '599 patent may not sustain a rejection under 35 U.S.C. §102(b) given each of the pending independent claims recites an element (i.e., a sublingual dosage form) the Examiner *admits* is missing from the art cited in support of the pending rejection raised under 35 U.S.C. §102(b). The Applicant, therefore,

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<sup>1</sup> No new matter is introduced through these new claims. Examples supporting a rapid dissolving sublingual dosage form are found in the specification at: page 4, ll. 11-14 and pages 23-24. The treatment of "breakthrough" pain, proximal to a diagnosis of cancer, is discussed at: page 8, ll. 17 –24.

<sup>2</sup> Office Action mailed 10/06/04, page 4.

respectfully requests the pending rejection under 35 U.S.C. §102(b) be withdrawn.

**2. The Claims Are Not Obvious**

In order to advance business interest and without acquiescing to the Examiner's arguments, while expressly reserving the right to prosecute the same (or similar) claims in subsequently filed applications, the Applicant has cancelled claims 1 - 8. Therefore the Applicant confines the rebuttal, to the rejections raised under 35 U.S.C. 103(a), in view of the currently claimed embodiments of the present invention which recite the administration of a rapid dissolving *sublingual dosage form* comprising tramadol and propoxyphene.<sup>3</sup>

**A. The Examiner Fails to Make A *Prima Facie* Case of Obviousness**

The Examiner is reminded that a *prima facie* case of obviousness requires citation to a combination of references which (a) disclose the elements of the claimed invention, (b) suggests or motivates one of skill in the art to combine those elements to yield the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of the these three requirements precludes a finding of a *prima facie* case of obviousness, and, without more, entitles Applicant to allowance of the claims in issue. See, e.g., *Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

The Applicant respectfully submits the Examiner has failed to establish each of the three elements of a *prima facie* case of obviousness. In addressing this rejection, the Applicant has focused on independent claims 9 and 12; since non-obviousness of an independent claim necessarily leads to non-obviousness of claims dependent there from. See, § MPEP 2143.03.

**i. No Motivation to Combine the References**

A proper analysis, in view of 35 U.S.C. §103(a), demands the references cited by the Examiner be considered as whole and must suggest the desirability and, thereby, the obviousness of making the combination. *Hodash v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143, n. 5, 229 USPQ 182, 187, n.5 (Fed. Cir. 1986). The Applicant submits that references cannot be considered collectively until the Examiner points to some motivation to combine said references.

This analysis prevents the Examiner from using the instant specification to reconstruct, in

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<sup>3</sup> That is to say, the Examiner's rejection of claims 2 and 8 are now moot.

hindsight, the invention as claimed. The Federal Circuit has articulated the policy behind this analysis:

“[t]o prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.” See *In re Rouffet et al.*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998).

In the Office Action mailed on October 06, 2004 the Examiner stated,

“[I]t would have been obvious to one of ordinary skill in the art to formulate the composition comprising propoxyphene and tramadol taught by Oshlack *et al.* in the intranasal or sublingual formulation since Straub *et al.* teach each of the agents are well-known to be formulated in intranasal or sublingual formulation.”  
See, page 4.

As a threshold objection, the Applicant notes the alleged disclosure, by U.S. Patent 6,395,300 to Straub *et al.*, of: i) propoxyphene, ii) tramadol, and iii) the (individual) sublingual administration of these drugs are within the context of “laundry lists”. That is to say, the ‘300 patent recites *hundreds* of drugs suitable for incorporation into the porous matrices described.<sup>4</sup> Similarly the “suitable” routes of administration<sup>5</sup>, for these porous matrices, include almost every route known to Medicine. Without more particularity, vis-à-vis the application of the cited art to the Applicant’s invention as claimed, this reference is deficient. *In re O’Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673,1681 (Fed. Cir. 1988)(holding that “obvious to try” is not the proper standard).

Notwithstanding these deficiencies of the ‘300 patent, however, the Examiner fails to document *how* the cited art may teaches the administration of a rapid dissolving sublingual

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<sup>4</sup> U.S. Patent 6,395,300 B1, Cols. 4-7.

<sup>5</sup> “The porous matrices, or formulations thereof, are suitable for administration of drug by a variety of routes, for example, parenteral, mucosal, oral, topical/transdermal administration, for local, regional, or systemic effect. Examples of parenteral routes include intravenous, intraarterial, intracardiac, intrathecal, intraosseous, intraarticular, intrasynovial, intracutaneous, subcutaneous, and intramuscular administration. Examples of mucosal routes include pulmonary (intrarespiratory), buccal, sublingual, intranasal, rectal, and vaginal administration. The porous matrices also can be formulated for intraocular, conjunctival, aural, urethral, intracranial, intralesional, and intratumoral administration.” *Id.* at Col. 13, ll 17 – 29.

dosage form comprising tramadol and propoxyphene, wherein, said dosage form is formulated under conditions such that said dosage form disintegrates upon contact with the saliva of said subject.

**ii. The Examiner Must Point To Evidence**

The Examiner offers a conclusory argument suggesting the alteration / recombination of the cited art to recapitulate the invention as claimed. Specifically, the Examiner states that, "[o]ne would have been motivated to formulate the composition comprising propoxyphene and tramadol taught by Oshlack *et al.* to provide various selection of formulation administrable by each of the active agent to accommodate each of the patient's preference in route of administration."<sup>6</sup>

The *Rouffet* court, however, admonishes against such an unsupported statement. Indeed, the Federal Circuit stated:

"The Board did not . . . explain what specific understanding or technological principal within the knowledge of one of ordinary skill in the art would have suggested the combination. Instead, the Board merely invoked the high level of skill in the art. If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technological advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness." *Rouffet*, 47 USPQ2d at 1458.

As discussed above, and contrary to the Examiner's opinion, the cited art provides no motivation to combine the references to teach the rapid dissolving sublingual dosage form comprising tramadol and propoxyphene, wherein, the dosage form is formulated under conditions such that it disintegrates upon contact with the saliva of said subject.

That is to say, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation is found in either the references themselves or in the knowledge generally available to one of ordinary skill in the art. MPEP 2143.01 at 2100-98, citing *In re Fine*, 837 F.2d 1071, USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d

<sup>6</sup> Office Action mailed 10/06/05, p. 5.

1941 (Fed. Cir. 1992).

Unsupported speculation that a given references *might* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP 2143.01 at 2100-98, citing *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). The requirement that the Examiner make a showing of a suggestion, teaching or motivation is "an essential evidentiary component of an obviousness holding." *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998).

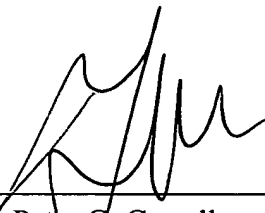
There are three sources for this evidentiary component: the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996). Nonetheless, regardless of the source of the requisite evidence, the Examiner's showing "must be clear and particular, and broad conclusory statements . . . standing alone, are not 'evidence'." *In re Dembiczak*, 175 F.3d 994, 1000 (Fed. Cir. 1999).

It is the Examiner's burden to present "evidence" and this showing must be "clear and particular." Importantly, since an Examiner is NOT one skilled in the art (under the law), the Examiner's opinion on what one skilled in the art might believe is of no moment. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) ("[T]he examiner's assumptions do not constitute the disclosure of the prior art."). In the instant prosecution, the Examiner suggest a motivation to combine an encyclopedic list of: i) drugs and ii) routes of administration (in the '300 patent) with oral formulations of opioids (in the '599 patent). The Examiner's suggestion, however, is insufficient evidence to document the motivation required to induce one, skilled in the art, to prepare the specific sublingual formulations recited in the methods as presently claimed by the Applicant. Accordingly, the pending claims should be allowed.

**CONCLUSION**

The Applicant believes the arguments set forth above traverse the Examiner's pending rejections and, therefore, requests these grounds for rejection be withdrawn. Should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned collect.

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